"Express Mail" Mailing Label Number: EV 341151 7680 S

Date of Deposit: July 9, 2003

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner For Patents, P.O. Box 1450,

Alexandria, VA 22313-1459

[Sender's Name] KAREN FORSYTH

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Richard H. Bruce, et al.

FOR

APPARATUS AND METHOD FOR

DETECTING AND LOCATING RARE CELLS

SERIAL NO.

Unknown

FILED

Herewith

EXAMINER

Unknown

ART UNIT

Unknown

LAST OFFICE ACTION

N/A

ATTORNEY DOCKET NO.

D/A2247I

XERZ 200563-3

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 C.F.R. §§ 1.56, 1.97, 1.98 and MPEP § 609, applicant(s) submit(s) the following Disclosure Statement concerning art of which the applicant(s) is(are) aware. A copy of PTO-1449 is enclosed herewith.

Under § 1.98(a)(3), no concise explanation of relevance is required for information that is in the English language. Accordingly, the enclosed patents require no further explanation (or no translation is available).

requested: WITHIN THREE MONTHS OF FILING: Under § 1.97(b)(1), this information disclosure \boxtimes statement is being filed within three months of the filing date of the application. Although it is believed no fee is necessary, any deficiency in fees should be charged to Deposit Account No. 24-0037. BEFORE FIRST OFFICE ACTION: Under § 1.97(b)(3), this information disclosure \Box statement is being filed before the mailing date of a first Office Action on the merits. Although it is believed no fee is necessary, any deficiency in fees should be charged to Deposit Account No. 24-0037. Under § 1.97(c)(2), this information shall be **BEFORE FINAL ACTION/WITH FEE:** considered if filed before the mailing date of a final action if accompanied by a fee in the amount of \$ as required by \$1.17(p). The required fees should be charged to Deposit Account No. 24-0037. INTERNATIONAL SEARCH REPORT: Under § 1.97(e)(1), the undersigned certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement. Although it is believed no fee is necessary, any deficiency in fees should be charged to Deposit Account No. 24-0037.

Consideration of the appropriate paragraph(s) indicated below is respectfully

Respectfully submitted,

FAY, SHARPE, FAGAN, MINNICH & McKEE, LLP

Mark S. Svat Reg. No. 34,261

1100 Superior Avenue

Seventh Floor

Cleveland, Ohio 44114-2579

(216) 861-5582

. . .

Substitute for form 1449/PTO

INFORMATION
DISCLOSURE STATEMENT
BY APPLICANT(S)

Atty. Docket No.: D/A2247I

XERZ 2 00563-3

Application No.: Unknown

First Named Inventor:

Richard H. Bruce, et al.

BY APPLICANT(S) (Use as many sheets as necessary)										
			Filing Date: Herewith				Examiner: N/A		Group: N/A	
US PATE	NT DO	CUMENTS								
Examiner Initials*	Cite No.	Document No.	Issue/Public	ation Date	Date Name of Pa Applicant of Ci			Pages, Columns, Lines, Whe Relevant Passages or Releva Figures Appear		
	AA	4,600,951	July 15, 1986		Blitchington					
	AB	4,849,645	July 18, 198	39	Mendenko et al.					
	AC	4,875,780	October 24,	1989	Moran et al.					
	AD	4,941,309	July 17, 1990		Masaharu et al.					
	AE	5,017,798	May 21, 1991		Murakami et al.					
	AF	5,216,485	June 1, 199	3	Bird et al.					
	AG	5,471,066	November 2	28, 1995	Hagiwara					
	AH	5,627,365	May, 6, 199	97	Chiba et al.					
	AI	5,640,246	June 17, 19	97	Castonguay					
	AJ	5,798,831	August 25, 1998		Hagiwara			<u> </u>		_
	AK	US2002/0186368 A1	December 1	12, 2002	Rosengaus et al.					
FOREIGN	PATE	NT DOCUMENT	S							
Examiner	Cite	Foreign Patent Docur	ment Date		Name of Patentee or Applicant of Cited Document		Pages, Col	umns, Lines, evant Passages or		
Initials*	No.	Country Code & Country Number							Figures Appear	
	AL	JP4296642	V	21OC1992						
	AM	JP6148085		27MY1994						
	AN	JP H9-145631 ✓		06JE1997						
	AO									
OTHER P	RIOR A	ART - NON PATI	ENT LITE	RATURE	DOC	UMENT	ΓS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published								
	AP	BIANCHI, Diana W., et al., Fetomaternal Cellular and Plasma DNA Trafficking, The York Academy of Sciences, pp. 119-131								ر ا
	AQ	WOLFE, Josh, A Thousand Dots of Light, Forbes/Wolfe Nanotech Report, May 29, 20								1
	AR	PERTL, Barbara, MD, et al., Fetal DNA in Maternal Plasma: Emerging Clinical Applications, <i>The American College of Obstetricians and Gynecologists</i> , Published by Elsevier Science Inc., Vol. 98, No. 3, September 2001, pp. 483-490								of

Examiner	Date Considered	
Signature		

Page 2 of 2

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT(S)

Atty. Docket No.: D/A2247 I

XERZ 2 00563-3

Application No.: Unknown

First Named Inventor:

Richard H. Bruce, et al.

(Use as many sheets as necessary)			Filing Date: Herewith			Examiner: N/A		Group: N/A		
U.S. PAT	ENT DO	CUMENTS								
Examiner Initials*	Cite No.	Document No.	Date		Name of Patentee or Applicant of Cited Document			Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	BA	6,545,334 B2	04/08/2003		Verhaegen					
	ВВ	5,892,577	04/06/1999		Gordon					
	ВС							<u> </u>		_
FOREIGN P	PATENT DO	OCUMENTS								_
Examiner Initials*	Cite No.	Foreign Patent Docum		Publication Date		Name of Patentee or Applicant of Cited Document		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	BD									\downarrow
	BE									\downarrow
	BF							-		\downarrow
	BG									1
OTHER	PRIOR A	ART - NON PATI	ENT LITE	RATURE	DOCU	JMENT	rs			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published								
	ВН	BAUER, Kenneth D., et al., Reliable and Sensitive Analysis of Occult Bone Marrow Metastases Using Automated Cellular Imaging, Clinical Cancer Research, Vol. 6, pp. 3552-3559, September 2000								
	BI	WITZIG, Thomas E., et al., Detection of Circulating Cytokeratin-positive Cells in the Blood of Breast Cancer Patients Using Immunomagnetic Enrichment and Digital Microscopy, Clinical Cancer Research, Vol. 8, 1085-1091, May 2002								
	BJ	GHOSSEIN, R.A., et al., Molecular Detection and Characterisation of Circulating Tumour Cells and Micrometastases in Solid Tumours, European Journal of Cancer 36 (2000) 1681-1694, March 2000, Elsevier Science Ltd.								
	ВК	FLATMARK, Kjersti, et al., Immunomagnetic Detection of Micrometastatic Cells in Bone Marrow of Colorectal Cancer Patients, Clinical Cancer Research, Vol. 8, 444-449, February 2002								
	BL	MÉHES, Gábor, et al., Quantitative Analysis of Disseminated Tumor Cells in the Bone Marrow by Automated Fluorescence Image Analysis, Cytometry (Communications in Clinical Cytometry), 42:357-362 (2000, Wiley-Liss, Inc.)								
	ВМ	WERTHER, M., et al., The Use of the CELLection Kit in the Isolation of Carcinoma Cells from Mononuclear Cell Suspensions, <i>Journal of Immunological Methods</i> , 238 (2000) 133-141, 2000 Elsevier Science B.V.								
	BN	BURCHILL, SA, et al., Comparison of the RNA-Amplification Based Methods RT-PCR and NASBA for the Detection of Circulating Tumour Cells, 2002Cancer Research Campaign, British Journal of Cancer (2002) 86, 102-109								

Examiner	Date Considered	
Signature		